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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/227,881      | 01/11/1999  | THAI D. NGUYEN       | 07425.0057          | 7578             |

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ARNOLD & PORTER LLP  
ATTN: IP DOCKETING DEPT.  
555 TWELFTH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

SCHULTZ, JAMES

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1635

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/227,881

Applicant(s)

NGUYEN ET AL.

Examiner

J. D. Schultz, Ph.D.

Art Unit

1635

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 18 March 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

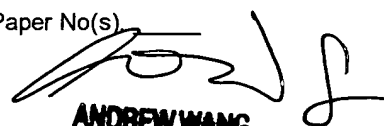
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 144, 146-155, 157-166 and 168-174.  
Claim(s) withdrawn from consideration: 145, 156, and 167, and subject matter of claims 145-154, 156-165, and 167-1.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_

  
**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Continuation of 3. NOTE: Applicants proposed amendment seeks to change the claim language in a manner that would require new considerations and thus require a new search. For example, the proposed amendment of claim 151 adds the limitation that the claimed fragment be capable of detecting a polymorphism at the TIGRmt1 site, which was not a limitation that had been previously claimed. Accordingly, because a new search would be required to examine this and other proposed claim amendments, entry of the amendment is denied.

Continuation of 5. Applicant's reply has overcome the following objection(s): The response overcomes the objection to the specification for adding new matter.

Continuation of 11. does NOT place the application in condition for allowance because: In regards to the argument that the restriction is improper, such arguments have been considered but are not convincing. Applicants have focused their arguments on the idea that because the complement of SEQ ID NO: 34 is useful with the sense strand of SEQ ID NO: 34, that the sequences cannot properly be restricted. This is not convincing, because the phrase "useful together" is interpreted in view of the use requirements provided by 35 U.S.C. § 101, which requires, among other things, that the use be specific and substantial. The disclosed use of SEQ ID NO: 34 with its complement is not considered to have specific or substantial utility, since any complement of any sequence can be used in a gel retardation assay, or PCR. Put another way, there is nothing specifically or substantially useful about a gel retardation assay of PCR, because these uses are not specific to that of SEQ ID NO: 34 and its complement, because any complement of any other transcript is also useful in these assays. Therefore, because applicants arguments are directed merely to showing that SEQ ID NO: 34 and its complement are useful in assays that any transcript and its complement are useful in, this is not considered to be sufficient to show that SEQ ID NO: 34 and its complement are useful together as required by statute. Furthermore, these arguments are considered moot in view of M.P.E.P. 2435, which sets forth that "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141." It is clear that SEQ ID NO: 34 and the complement of SEQ ID NO: 34, if translated, encode different proteins. Accordingly, restriction is proper therefore.

Regarding the arguments that the claims drawn to any fragment of SEQ ID NO: 34 possess written description because the specification provides domains of SEQ ID NO: 34 that have regulatory function, as well as fragments that may be used in gel retardation assays, PCR, and single sequence conformation studies, these arguments are not considered convincing because the rejection is based on the fact that no common structure of the genus of such fragments has been taught that relates to the disclosed functions have been taught, as required by statute and clarified at M.P.E.P. 2163. While the specification does describe numerous functional regulatory regions, and also discloses assays that might utilize fragments of SEQ ID NO: 34, No common structure is taught one of skill would not be able to envision the genus of such fragments, and accordingly, one of skill would not be convinced that applicants were in possession of the genus as claimed.